Prevaccination Checklist for COVID-19 Vaccines

Information for Healthcare Professionals

The following guidance should be used to determine if COVID-19 vaccine can be administered or not, based on the recipients answers to checklist questions. Using the completed prevaccination checklist, review clinical guidance based on the answers to the questions. Use this document in conjunction with:

- Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States at www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html
- Advisory Committee on Immunization Practices on Immunization General Best Practice Guidelines at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html

COVID-19 vaccines are authorized and approved for different age groups. Administer COVID-19 vaccine intramuscularly.

For guidance on specific schedules, storage, preparation, and administration, please see:

- Interim COVID-19 Immunization Schedule for Ages 5 Years and Older at www.cdc.gov/vaccines/covid-19/downloads/COVID-19-immunization-schedule-ages-5yrs-older.pdf
- COVID-19 Vaccination Clinical & Professional Resources for each vaccine product at www.cdc.gov/vaccines/covid-19/info-by-product/index.html

Postvaccination Observation Times for People without Contraindications to COVID-19 Vaccination

30 minutes:

- People with a history of:
  - Contraindication to another type of COVID-19 vaccine product due to allergy
  - Immediate (within 4 hours of exposure) non-severe allergic reaction to other (non-COVID-19 vaccines) or injectable therapies.
  - Anaphylaxis due to any cause
  - Non-severe allergic reaction to a previous dose of that same type of COVID-19 vaccine

15 minutes:

- All other people

Co-administration of COVID-19 vaccines and other vaccines

COVID-19 vaccines and other vaccines **may be administered without regard to timing.** This includes simultaneous administration of COVID-19 vaccines and other vaccines during the same visit. Other vaccines can also be administered anytime before or after COVID-19 vaccination.

1. How old are you?

Clinical considerations based on the age of the recipient include:

COVID-19 vaccines products have different age indications. Janssen, Moderna and Pfizer-BioNTech (Gray and purple caps) products can be administered to persons 18 years of age and older. Only Pfizer-BioNTech vaccine products can be administered to children 5 – 11 years of age (orange cap) and 12 – 17 years of age (purple or gray caps).

People receiving mRNA COVID-19 vaccines, especially males ages 12–39 years, should be made aware of the rare risk of myocarditis and/or pericarditis following receipt of mRNA COVID-19 vaccines and the benefit of COVID-19 vaccination in reducing the risk of severe outcomes from COVID-19, including the possibility of cardiac sequelae. Counseling should include the need to seek care if symptoms of myocarditis or pericarditis, such as chest pain, shortness of breath, or tachycardia develop after vaccination, particularly in the week after vaccination. Extending the interval between the first and second mRNA vaccine dose to 8 weeks might reduce the risk.

Additional recipient education materials can be found at www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html

2. Are you feeling sick today?

While there is no evidence acute illness reduces vaccine efficacy or increases adverse reactions, as a precaution, **delay vaccinating patients with moderate or severe illness** until the illness has improved.

Defer vaccination of people with current SARS-CoV-2 infection. For those with:

- Symptoms defer vaccination until recovery from the acute illness and isolation has been discontinued.
- Asymptomatic infection, defer vaccination until isolation has been discontinued.

This recommendation applies regardless of whether the SARS-CoV-2 infection occurred before the recipient received an initial dose or between doses. Viral or serological testing to assess for current or prior infection solely for the purpose of vaccine-decision making is not recommended.

People with mild illnesses can be vaccinated. Do not withhold vaccination if a person is taking antibiotics.

3. Have you ever received a dose of COVID-19 vaccine?

COVID-19 vaccination is recommended for everyone 5 years of age and older. All COVID-19 primary series doses should be the same vaccine product. Booster doses, for eligible persons, may be a different product than the COVID-19 vaccine product used in the primary series (i.e., mix and match may be used for boosters).

To determine previously administered COVID-19 doses, check medical records, immunization information systems, and vaccination record cards to help determine the initial product received. If the vaccine product for a primary mRNA dose cannot be determined or is no longer available, any available mRNA vaccine may be administered (separate doses by at least 28 days). If a different mRNA COVID-19 vaccine is inadvertently administered for the primary series or additional primary dose, the dose is considered valid, and no additional doses of either product are recommended.

Detailed immunization schedule information can be found at Interim COVID-19 Immunization Schedule for Ages 5 Years and Older at www.cdc.gov/vaccines/ covid-19/downloads/COVID-19-immunization-schedule-ages- 5yrs-older.pdf

Persons who are NOT moderately or severely immunocompromised

Age Group	Vaccine Product	Primary Series*	Primary Series Dosage (Amount)	Booster Dose*	Booster Dosage (Amount)
5–11 years	**Pfizer-BioNTech** *(Orange Cap)*	2 doses, separated by at least 3 weeks	0.2 mL	Booster dose 1: At least 5 months after the previous dose Booster dose 2: N/A	0.2 mL
12 years and older	**Pfizer-BioNTech** *(Purple Cap or Gray Cap)*	2 doses separated by 3–8 weeks†	0.3 mL	Booster dose 1: At least 5 months after previous dose Booster dose 2: At least 4 months after previous dose for persons ages 50 years and older	0.3 mL
18 years and older	**Moderna**	2 doses separated by 4–8 weeks†	0.5 mL	Booster dose 1: At least 5 months after previous dose Booster dose 2: At least 4 months after previous dose for persons ages 50 years and older	0.25 mL
	Janssen‡	1 dose	0.5 mL	Booster dose 1: At least 2 months after the primary series dose Booster dose 2§: At least 4 months after previous dose for persons 50 years of age and older. (mRNA vaccine only)	0.5 mL

* Persons with a recent SARS-CoV-2 infection may consider delaying their first or second COVID-19 vaccine booster dose by 3 months from symptom onset or positive test (if infection was asymptomatic). See question 8 for additional information.

† An 8-week interval may be optimal for some people, including males 12-39 years of age because of the small risk of myocarditis associated with mRNA COVID-19 vaccines. Vaccine effectiveness may also be increased with an interval longer than 3 or 4 weeks (depending on the product). See question 1 for additional information.

‡ An mRNA vaccine (Moderna or Pfizer-BioNTech) is preferred to Janssen COVID-19 vaccine.

§ People ages 18-49 years: Those who received Janssen COVID-19 Vaccine as both their primary series dose and booster dose may receive a second booster dose using an mRNA COVID-19 vaccine at least 4 months after the Janssen booster dose.

Persons who ARE moderately or severely immunocompromised

See information outlined in question 4 for vaccination recommendations.

Persons who received COVID-19 vaccine outside the United States

The recommendations for people vaccinated outside the United States depend on the vaccine(s) received for the primary series, whether the primary series was completed, and whether a booster dose was received. Current guidance can be found at: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#appendix-a

Additional information including scheduling, immunocompromising conditions and treatments can be found in:

Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States: www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

Interim COVID-19 Immunization Schedule for Ages 5 Years and Older at www.cdc.gov/vaccines/covid-19/downloads/COVID-19-immunization-schedule-ages-5yrs-older.pdf

4. Do you have a health condition or are you undergoing treatment that makes you moderately or severely immunocompromised?

People with immunocompromising conditions or people who take immunosuppressive medications or therapies are at increased risk for severe COVID-19 disease. COVID-19 vaccines may be administered to people with underlying medical conditions, such as HIV infection or other immunocompromising conditions, or who take immunosuppressive medications or therapies, who have no contraindications to vaccination. People can self-report if they are moderately or severely immunocompromised. Vaccinators should not deny COVID-19 vaccination to a person due to lack of documentation of immune status. **A 3-dose primary series followed by a booster dose is recommended for these persons 5 years of age and older. Persons 12 years of age and older should receive a 2nd booster dose.**

An mRNA COVID-19 vaccine is preferred over Janssen COVID-19 Vaccine. The same mRNA vaccine product should be used for all primary series doses. If the vaccine product for a primary mRNA dose cannot be determined or is no longer available, any available mRNA vaccine may be administered (separate doses by at least 28 days). If a different mRNA COVID-19 vaccine is inadvertently administered for the primary series or additional primary dose, the dose is considered valid, and no additional doses of either product are recommended.

Vaccinated people who are moderately or severely immunocompromised should be counseled about the potential for a reduced immune response to COVID-19 vaccines. They and their close contacts should continue to follow current prevention measures (www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html).

Persons who ARE moderately or severely immunocompromised

Age Group	Vaccine Product	Primary Series	Primary Series Dosage (Amount)	Booster Dose	Booster Dosage (Amount)
5–11 years	**Pfizer-BioNTech** *(Orange Cap)*	3 doses, separate: Dose 1 and 2 by at least 3 weeks Dose 2 and 3 by at least 4 weeks	0.2 mL	Booster dose 1: At least 3 months after the previous dose Booster dose 2: n/a	0.2 mL
12 years and older	**Pfizer-BioNTech** *(Purple Cap or Gray Cap)*	3 doses, separate: Dose 1 and 2 by at least 3 weeks Dose 2 and 3 by at least 4 weeks	0.3 mL	Booster dose 1: At least 3 months after the previous dose Booster dose 2: At least 4 months after the previous dose	0.3 mL
18 years and older	**Moderna**	3 doses, separate: Dose 1 and 2 by at least 4 weeks Dose 2 and 3 by at least 4 weeks	0.5 mL	Booster dose 1: At least 3 months after the previous dose Booster dose 2: At least 4 months after the previous dose	0.25 mL
	Janssen*	1 Janssen, followed by 1 mRNA vaccine Separate doses by at least 4 weeks	0.5 mL	Booster dose 1: At least 2 months after the previous dose Booster dose 2: At least 4 months after the previous dose (mRNA vaccine only)	0.5 mL

* An mRNA vaccine (Moderna or Pfizer-BioNTech) is preferred to Janssen COVID-19 vaccine.

Additional information including scheduling, immunocompromising conditions and treatments can be found in:

Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States: www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

Interim COVID-19 Immunization Schedule for Ages 5 Years and Older at www.cdc.gov/vaccines/covid-19/downloads/COVID-19-immunization-schedule-ages-5yrs-older.pdf

5. Have you received a hematopoietic cell transplant (HCT) or CAR-T-cell therapy since receiving COVID-19 vaccine?

HCT and CAR-T-cell recipients who received doses of COVID-19 vaccine before or during HCT or CAR-T-cell therapy should be revaccinated with a primary vaccine series at least 3 months (12 weeks) after transplant or CAR-T-cell therapy. Additional information can be found at: Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#immunocompromised

6. Have you ever had an allergic reaction to:

- A component of a COVID-19 vaccine
- A previous dose of COVID-19 vaccine

People with a severe allergic reaction* to a previous COVID-19 vaccine dose or a known (diagnosed) allergy to a component of the vaccine have a contraindication to vaccination. People who had an immediate (< 4 hours), but non-severe allergic reaction to a previous dose of COVID-19 vaccine, have a precaution to receiving the same type of COVID-19 vaccine product. Although they can receive the same product, a different COVID-19 vaccine product can also be administered.

People with a contraindication to one type of COVID-19 vaccine (e.g., mRNA) should not receive any doses of that type of vaccine and have a precaution to the other type of vaccine (e.g., Janssen viral vector). People with a history of immediate allergic reaction to any vaccine other than COVID-19 vaccine or injectable therapy that contains multiple components, one or more of which is a component of a COVID-19 vaccine, have a precaution to vaccination with that COVID-19 vaccine, even if it is unknown which component elicited the allergic reaction.

COVID-19 Vaccine Components†

Description	**Pfizer-BioNTech** mRNA COVID-19 Vaccine		**Moderna** mRNA COVID-19 Vaccine	**Janssen** COVID-19 Vaccine
	For 5-11 years formulation (Orange Cap) and 12 years and older formulation (Gray Cap)	For 12 years and older formulation (Purple Cap)		
Active ingredients	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2		Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Recombinant, replication-incompetent Ad26 vector, encoding a stabilized variant of the SARS-CoV-2 Spike (S) protein
Inactive ingredients	2[(polyethylene glycol {PEG})-2000]-N, N-ditetradecylacetamide		PEG2000-DMG: 1,2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol	Polysorbate-80
	1,2-distearoyl-sn-glycero-3-phosphocholine		1,2-distearoyl-sn-glycero-3-phosphocholine	2-hydroxypropyl-β-cyclodextrin
	Cholesterol		Cholesterol	Citric acid monohydrate
	(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl) bis(2-hexyldecanoate)		SM-102: heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate	Trisodium citrate dihydrate
	Tromethamine	Sodium chloride	Tromethamine	Sodium chloride
	Tromethamine hydrochloride	Monobasic potassium phosphate	Tromethamine hydrochloride	Ethanol
	Sucrose	Potassium chloride	Acetic acid	
		Dibasic sodium phosphate dihydrate	Sodium acetate	
		Sucrose	Sucrose	

* When vaccine recipients report a history of an immediate allergic reaction, providers should attempt to determine whether reactions reported following vaccination are consistent with immediate allergic reactions versus other types of reactions commonly observed following vaccination, such as vasovagal reaction or postvaccination side effects (which are not contraindications to receiving the second of an mRNA COVID-19 vaccine dose).

† None of the vaccines contain eggs, gelatin, latex, or preservatives.

Potential characteristics of allergic reactions, vasovagal reactions, and vaccine side effects following COVID-19 vaccination

In patients who experience post-vaccination symptoms, determining the etiology (including allergic reaction, vasovagal reaction, or vaccine side effects) is important to determine whether a person can receive additional doses of the vaccine. Additional information can be found at Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html

Healthcare professionals should be familiar with identifying severe allergic reactions, including anaphylaxis, and be competent in treating these events at the time of vaccine administration. Appropriate medical treatment for severe allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of a COVID-19 vaccine. See Management of Anaphylaxis at COVID-19 Vaccination Sites for additional guidance.
https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html

Syncope may occur in association with injectable vaccines, in particular among adolescents. Procedures should be in place to avoid falling injuries and manage syncopal reactions. All people are recommended to be observed following COVID-19 vaccination for at least 15 minutes. Patients should be seated or lying down for vaccination and during the observation period to decrease the risk for injury should they faint. If syncope develops, patients should be observed until symptoms resolve.

7. Have you ever had an allergic reaction to another vaccine (other than COVID-19 vaccine) or another injectable medication?

A history of any immediate allergic reaction (onset <4 hours of exposure) to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies not related to a component of COVID-19 vaccines) is a precaution to currently FDA-authorized or -approved COVID-19 vaccines. This also applies if the non-COVID-19 vaccine or therapy has multiple components, one or more of which is a component of a COVID-19 vaccine, and it is unknown which component elicited the allergic reaction. Vaccine may be given, but counsel patients about unknown risks of developing a severe allergic reaction and balance these risks against the benefits of vaccination. Deferral of vaccination and/or consultation with an allergist-immunologist should be considered. Considerations for vaccination include risk of exposure to SARS-CoV-2, risk of severe disease or death due to COVID-19, previous infection with COVID-19, unknown risk of anaphylaxis following COVID-19 vaccination, and ability of recipient to receive care immediately for anaphylaxis, if necessary. **These individuals should be observed for 30 minutes after vaccination.**

8. Clinical Considerations:

Response	Consideration
History of myocarditis or pericarditis	▪ Development of myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine is a precaution to a subsequent dose of any COVID-19 vaccine and subsequent doses should generally be avoided. ▪ If after a risk assessment, the decision is made to receive a subsequent COVID-19 vaccine dose, the person should wait until after their episode has resolved. ▪ For men ages 18 years and older who choose to receive a subsequent COVID-19 vaccine, a Janssen COVID-19 Vaccine can be considered instead of mRNA COVID-19 vaccines. ▪ Persons who have a history of myocarditis or pericarditis unrelated to mRNA COVID-19 vaccination may receive any currently FDA-approved or -authorized COVID-19 vaccine after the episode of myocarditis or pericarditis has resolved.
History of multisystem inflammatory syndrome; either MIS-C (children) or MIS-A (adults)	▪ A history of multisystem inflammatory syndrome; either MIS-C (children) or MIS-A (adults) is a precaution to receipt of COVID-19 vaccine. ▪ Considerations when conducting a risk assessment for potential COVID-19 vaccination can be found at www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#infection ▪ Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment Project at www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html.
History of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as heparin-induced thrombocytopenia (HIT)	▪ With a history of an episode of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as spontaneous or classic HIT, should not receive Janssen COVID-19 vaccine. ▪ These persons should receive another current FDA-authorized or -approved mRNA COVID-19 vaccine
History of thrombosis with thrombocytopenia syndrome (TTS)	▪ It is contraindicated to administer Janssen COVID-19 Vaccine to persons with a history of TTS following receipt of the Janssen COVID-19 Vaccine or any other adenovirus vector-based COVID-19 vaccines (e.g., AstraZeneca's COVID-19 Vaccine) ▪ These persons should receive an mRNA vaccine for all subsequent doses. ▪ Prior to booster vaccination, a conversation between the patient and their clinical team, including hematologists or other specialists, may assist with vaccination decisions
History of Guillain-Barré Syndrome (GBS)	▪ A history of GBS, either before or after COVID-19 vaccination, is a precaution for receipt of Janssen COVID-19 Vaccine. An mRNA vaccine is preferred. ▪ Persons who develop GBS within 6 weeks of Janssen COVID-19 vaccination should only receive an mRNA COVID-19 vaccine for subsequent doses.
History of prior COVID-19 disease	▪ COVID-19 vaccination is recommended for everyone ages 5 years and older, regardless of a history of symptomatic or asymptomatic SARS-CoV-2 infection. People who recently had COVID-19 disease or SARS-CoV-2 infection (within the last 3 months) may consider **delaying their first or second booster dose by 3 months from symptom onset or positive test (if infection was asymptomatic)**. ▪ Studies have shown that increased time between infection and vaccination may result in an improved immune response to vaccination. Also, a low risk of reinfection has been observed in the weeks to months following infection. Individual factors such as risk of severe disease, COVID-19 community level, or characteristics of the predominant SARS-CoV-2 strain should be considered when determining whether to delay getting a booster dose after infection. ▪ **NOTE: Viral testing to assess for acute SARS-CoV-2 infection or serologic testing to assess for prior infection is NOT RECOMMENDED for the purpose of vaccine decision-making.**